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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,091	12/07/2000	Jing-Hui Tian	7969-088-999	3097

20583 7590 07/16/2004

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EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/732,091	TIAN ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2000*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) *6-40,43-56,60-68,70-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,41,42,57-59 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/7/2000;9/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amended Claims 1-78 are pending.

2. Claims 1-5,41,42,57-59,69 are under consideration, in so far as the claims recite the elected HP30 polypeptide.

3. Claims 6-40, 43-56,59-68, 70-78, recite non-elected inventions or species of nonelected inventions.

Election/Restrictions

4. Applicant's election with traverse of Group I, species 1, 30 kDa protein in the reply filed on April 2, 2004 is acknowledged.

5. The traversal is on the ground(s) that the examination of the entire application cannot constitute a serious burden. These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I-XIX are drawn to distinct inventions which are related as separate products capable of separate functions. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-XIX are classified separately necessitating different searches of issued US Patents.

However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example nucleic acid molecules structurally and functionally differ from polypeptide structures and biological functions. Additionally, it is submitted that the inventions of Groups I-XIX have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group. For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

1. Claims 6-40, 43-56,59-68, 70-78, in so far as the claims recite a non-elected invention or species of invention, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II-XIX and independent and distinct species of Group I invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 2, 2004.

2. Claims 1-5,41,42,57-59,69 are under consideration, in so far as the claims recite the elected HP30 polypeptide.

Claim Objections

3. Claims 1-5,41,42,57-59,69 are objected to because of the following informalities: Claims 1-5,41,42,57-59,69 recite non-elected embodiments of invention that are not under consideration or examination .

4. Claim 41 recites the phrase "one or more of an isolated HP30 polypeptide". As only a single polypeptide is recited in the claim, in light of the amendment to delete the HP56 polypeptide, and the elected invention is the HP30 polypeptide, the recited introductory phrase set forth in claim 41 is no longer applicable to defining the invention. Claim 41 recites a semi-colon "; " on line 4, this defines the beginning of a separate invention which should be removed.

5. Claim 41 recites various abbreviations such as "QS21, MF59, CPG," "PML "and "PLG"; the meaning of these terms should be provided in the claims at their first appearing. While the

specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

6. Appropriate correction is required.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 57-59,69 (not including the withdrawn optional embodiments which are drawn to a withdrawn non-elected invention) are rejected under 35 U.S.C. 102(b) as being anticipated by Tomb et al (1997).

Tomb et al disclose an isolated Helicobacter polypeptide, designated HP1588 (see Table 2, column 3, middle of column and Embl accession number D64718, created date August 9, 1997) encoded by an isolated nucleic acid, wherein the polypeptide was expressed recombinantly, and is a conserved protein that shares 100% sequence identity with SEQ ID NO 4, which is encoded by a nucleic acid sequence of SEQ ID NO 3.

The isolated polypeptide about 30 kDa polypeptide obtained from Helicobacter pylori strain 26695, also known as ATCC 700392, anticipates the instantly claimed invention.

3. Claims 1-5,41,42,57-59,69 (not including the withdrawn optional embodiments which are drawn to a withdrawn non-elected invention) are rejected under 35 U.S.C. 102(b) as being anticipated by WO96/40893 (1996; Accession number AAW20486).

WO96/40893 discloses an isolated Helicobacter polypeptide, encoded by an isolated nucleic acid, wherein the polypeptide was expressed recombinantly, and is an HP30 polypeptide that shares identity with SEQ ID NO 4, and is encoded by a sequence of SEQ ID NO 3. The isolated polypeptide of about 30 kDa polypeptide obtained from Helicobacter pylori anticipates the instantly claimed invention.

WO96' also discloses a method of stimulating an immune response to the H.pylori polypeptides, through formulating an immunogenic composition that comprises an adjuvant (see page 84, paragraphs 4-5, page 85, paragraphs 2-4) or carrier, wherein the adjuvants and carriers disclosed to include polylactide-glycolide microspheres (PLG microspheres), saponins (include the species represented by QS21), labile toxin of E.coli includes mLT, aluminum hydroxide includes alum.

A method that comprises the step of administering the immunogenic compositions to a mammal (animal; see page 84, last paragraph bridging to page 85, paragraph) is also disclosed. The reference anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomb et al in view of WO96/40893.

Tomb et al teach and show a 30 kDa Helicobacter pylori conserved polypeptide, produced recombinantly in a transformed host cell, a type of composition, the polypeptide comprising SEQ ID NO 4. The reference fails to show the polypeptide formulated into an immunogenic composition which is administered to a patient for induction of an immune response.

WO96' teaches a 30 kDa Helicobacter pylori polypeptide for formulation into an immunogenic composition and teaches the methods step of administering an immunogenic composition to an animal in an analogous art for the purpose inducing antibodies directed to Helicobacter pylori polypeptides, that antibodies being directed against a human pathogen associated with gastric ulcers and cancer.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the composition of Tomb et al in view of the guidance and teaching of WO96, to produce immunogenic compositions that comprise a 30 kDa polypeptide together with an adjuvant, and the administration of the polypeptide to a patient to induce an immune response, because both Tomb et al and WO96' teach H.pylori polypeptides associated with a known human pathogen and WO96' teaches the importance of producing, and administering immunogenic compositions that comprise H.pylori polypeptides for the induction of an immune response because the induced immune response defines a tool for gaining greater insight into the pathogenesis of H.pylori (see WO96, page 83, paragraphs 2-4).

The person of ordinary skill in the art would have had a reasonable expectation of success of formulating the H.pylori 30 kDa polypeptides into immunogenic compositions and administrating the compositions to an animal because WO96' provides extensive guidance for making and using immunogenic compositions and shows the successful induction of an immune response to an immunogenic composition that comprises a H.pylori polypeptide (page WO96' 103). Tomb et al in view of WO96' obviate the instantly claimed invention.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

7. Alemohammad (US Pat. 5,262,156); Blaser et al (US Pat.5,459,041); Pronovost et al (US Pat. 5,814,455 and 5,846,751) are cited to show compositions of Helicobacter pylori antigens of about 30 kDa.

8. Madico et al (June 1995, abstract) ; Andersen et al (1995, abstract) and Johansen et al (abstract 1995) are cited to show 30 kDa antigens of Helicobacter pylori.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
July 7, 2004

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